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**REMARKS**

This Amendment is in response to the Office Action mailed September 27, 2002, wherein claims 1-24 were rejected under 35 U.S.C. §103(a) as being obvious over U.S. 6,248,110 to Reiley et al (Reiley) in view of U.S. 5,549,679 to Kuslich et al (Kuslich).

In regard to claims 1-20, the Office Action indicated that the methods claimed therein would have been obvious in light of Reiley and Kuslich because the steps carried out in the claimed methods would be obviously carried out during the operation of the device described in claims 21-24.

It must initially be noted that as indicated above, claims 21-24 have been cancelled from the Application.

As to the assertion that the methods of claims 1-20 would be obvious in light of Reiley in view of Kuslich, Applicants must respectfully disagree.

When an attempt is made to combine two references, or to change a single reference, a *prima facie* case of obviousness has not been established if the intended purpose or function of either reference is destroyed by their combination (See generally *Hodosh v. Block Drug Co.*, 786 F.2d 1136, 229 USPQ 182, 187 (Fed. Cir. 1986) citing *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

In regard to the Kuslich reference, Kuslich describes a bag that is implanted within a spinal body and requires the use of a bag material that will allow ingress and egress of fluids and solutions that will allow the ingrowth and through growth of blood vessels, tissue and bone, but which has a tight enough weave or holes to retain small particles within the bag (column 7, lines 8-17 and 41-43). In Kuslich, the bag is used in a method for stabilizing a spinal motion segment by inserting into the bag into the spinal body where it is packed with material to promote the union of the adjacent spinal bodies through the bag. It is inherent that the bag is left within the spinal body in order to promote such bone fusion (column 11, lines 51-60; see also claims 1-4).

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The purpose and function of the method and apparatus described in Kuslich is contrasted by those of Reiley. In Reiley the body 56 is merely an expandable body that is expanded within a vertebral body 26 and then subsequently collapsed and removed from the body after a period of three to five minutes (column 8, lines 61-66). Nothing in the Reiley reference teaches or suggests that the body 56 is equipped with a plurality of openings to promote bone fusion through the body 56. As a result, body 56 would be incapable for use in any method or procedure involving long term implantation of the body 56 into a body space, or that the body 56 itself could allow ingress and egress of fluids and solutions that will allow the ingrowth and through growth of blood vessels, tissue and bone therethrough.

As a result of the significant differences between the method and apparatuses described in Kuslich and Reiley respectively, it is clear that if body 56 of Reiley were combined with the bag of Kuslich as proposed in the Office Action, the resulting hybrid device would be incapable of being implanted within a body to promote fusion between adjacent spinal bodies as the hybrid device would be incapable of allowing ingrowth and through growth of blood vessels, tissue and bone therethrough.

Because the proposed combination of the cited references would result in the intended functionality of at least one of the references being destroyed, the §103 obviousness based upon their proposed combination cannot be maintained and is thus, respectfully overcome.

The §103 obviousness rejection as asserted in the Office Action is believed to be overcome without necessitating any amendments to claims 1-20. However, for reasons unrelated to the rejection stated in the Office Action, Applicants have amended claims 1, 11 and 13. The amendment to claim 13 necessitated the cancellation of claim 14. The amendment to claim 1 removes the need to affirmatively close the fill opening. As described in the specification and stated in dependent claim 9 the bag used in the method claimed may be capable of being self-closing, no narrowing is intended. Claim 11 has been amended to clarify the claim and the

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function of the steps described, no narrowing is intended. Claim 13 has been amended to clarify the need to remove the body from the bag following expansion of the body, no narrowing is intended

**FORMALITIES**

If an extension of time is required to make this response timely and no separate petition is enclosed, Applicants hereby petition for an extension of time sufficient to make the response timely. In the event that this response requires the payment of government fees and payment is not enclosed, please charge Deposit Account No. 22-0350.

**CONCLUSION**

In view of the foregoing it is believed that the present application, with claims 1-13 and 15-20 is in condition for allowance. Early action to that effect is earnestly solicited.

Respectfully submitted,  
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Date: 1/27/03

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**MARKED COPY OF THE AMENDED CLAIMS**

Please cancel claims 14, 21-24 from the Application without prejudice or disclaimer.

Please replace claim 1 with the following amended claim:

1. (Amended) A method of treating a bone abnormality in a body comprising the following steps:
  1. exposing an area of bone having an abnormality;
  2. forming at least one cavity in the bone, wherein a portion of the at least one cavity defines an opening;
  3. inserting an expandable, empty fabric bag into the at least one cavity through the opening, the bag being formed of a fabric wall that includes a plurality of bag openings between about 0.25 to about 5.0 mm in diameter, the bag defining an interior and having an exterior; and
  4. packing the bag through a fill opening with material that will support or promote bone growth through the fabric wall, the packing causing said bag to expand until the bag and material combination form a self-retaining rigid shape wherein the exterior of the bag is substantially in contact with the bone of the cavity, the plurality of bag openings constructed and arranged to substantially prevent the material from passing from the interior of the bag to the exterior of the bag[; and
  5. closing said fill opening to prevent loss of the material from the bag interior].

Please replace claim 11 with the following amended claim:

11. (Amended) The method of claim 1 wherein formation of the cavity comprises the following steps:
  1. boring into the area of the bone to form the opening;

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inserting an expandable compaction member into the opening; and  
[inflating] expanding the compaction member, wherein by expanding the  
compaction member [thereby compacting] a quantity of bone adjacent thereto is compacted, the  
compaction of the quantity of bone [being sufficient to form] forming the cavity.

Please replace claim 13 with the following amended claim:

13. (Amended) The method of claim 1 further comprising the following steps:

disposing the fabric bag about a body adapted to assume a collapsed geometry for deployment into the bag, the body being expandable to an expanded geometry for compacting cancellous bone; [and]

expanding the body within the bag, the expansion of the body expanding the bag;  
and

removing the body from the bag after the body is expanded to the expanded  
geometry.